DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
Endoscopy Division
Mr. Nicholas Condakes
Regulatory Affairs Specialist
160 Dascomb Road
Andover, MA 01810

JUL 27 2015

Re: K000717
Trade/Device Name: SutureLok
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated (Date on orig SE ltr): February 29, 2000
Received (Date on orig SE ltr): March 3, 2000

Dear Mr. Condakes,

This letter corrects our substantially equivalent letter of March 30, 2000.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement K000717

510(k) Number (if known)

Device Name Smith & Nephew SutureLok

Indications for Use The Smith & Nephew SutureLok is indicated for use in open and endoscopic procedures, including thoracoscopic surgery, laparoscopic procedures and general surgery. The device is not indicated for use in contraception tubal ligation.

Intended Use The Smith & Nephew SutureLok is intended for use in conjunction with USP size 0, 2-0 and 3-0 braided silk, nylon or polyester non-absorbable sutures in the management of soft vessel ligation and/or fixation of soft tissue structures during open and endoscopic procedures.

MRO for CMD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000717

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR § 801.109)

K000717

Section V

MAR 3 0 2000

510(k) Summary
Special 510(k):
Date Prepared: February 29, 2000

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc., Endoscopy Division
160 Dascomb Road
Andover, Massachusetts 01810

B. Company Contact

Nicholas Condakes
Regulatory Affairs Specialist

C. Device Name

Trade Name: Smith & Nephew SutureLok
Common Name:

- Suture Retention Device
- Endoscope Accessory
- Laparoscope Accessory

Classification Name:

- Suture Retention Device (KGS)
- Endoscope Accessory (GCJ)
- Laparoscope Accessory (HET)

D. Predicate Devices

The Smith & Nephew SutureLok is substantially equivalent in design, materials, function and intended use to the following devices in commercial distribution:

Smith & Nephew SutureLok-K991500

E. Description of Device

The Smith & Nephew SutureLok comprises three main components:

- The suture Lok implant (ring and pin)
- The disposable cartridge assembly with threader, and
- The reusable delivery instrument

F. Indications for Use

The Smith & Nephew SutureLok is indicated for use in open and endoscopic procedures, including thoracoscopic surgery, laparoscopic procedures and general surgery. The device is not indicated for use in contraception tubal ligation.

K000717

G. Intended Use

The Smith & Nephew SutureLok is intended for use in conjunction with USP size 0, 2-0 and 3-0 braided silk, nylon or polyester non-absorbable sutures in the management of soft vessel ligation and/or fixation of soft tissue structures during open and endoscopic procedures.

H. Comparison of Technological Characteristics

The Smith & Nephew SutureLok is identical to the predicate device in its intended use, and similar in safety and effectiveness. The only difference between the new implant and the predicate device is that the Lock Ring outside diameter is redesigned to add a titanium sleeve and to increase distal end material thickness.

Comparative strength testing demonstrated the equivalence of the SutureLok to the predicate device.

Nicholas Condakes

Nicholas Condakes
Regulatory Affairs Specialist